# Complete Summary

## GUIDELINE TITLE

HIV disease management.

## BIBLIOGRAPHIC SOURCE(S)

Texas Tech University Managed Health Care Network Pharmacy & Therapeutics Committee. HIV disease management. Conroe (TX): University of Texas Medical Branch Correctional Managed Care; 2002 Jul. 7 p. [3 references]

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Opportunistic infections:
  - Pneumocystis carinii pneumonia
  - Toxoplasmic encephalitis
  - Cryptosporidiosis
  - Tuberculosis
  - Infection with Mycobacterium avium complex
  - Bacterial enteric infections
  - Candidiasis
  - Cryptococcosis
  - Histoplasmosis
  - Coccidioidomycosis
  - Cytomegalovirus disease
  - Herpes simplex virus disease
  - Varicella-zoster virus infection
  - Human papillomavirus infection
  - Hepatitis B virus infection
  - Influenza

## GUIDELINE CATEGORY

Evaluation
Management
Treatment

## CLINICAL SPECIALTY

Family Practice
Internal Medicine

## INTENDED USERS

Health Care Providers
Physicians

## GUIDELINE OBJECTIVE(S)

To present recommendations for the management and treatment of human immunodeficiency virus (HIV) infection in incarcerated offenders within the Texas Department of Criminal Justice

## TARGET POPULATION

Incarcerated offenders infected with human immunodeficiency virus (HIV) within the Texas Department of Criminal Justice

## INTERVENTIONS AND PRACTICES CONSIDERED

1. Medical history, including sexual history, social history, medication history, and history of opportunistic infections
2. Physical examination, including vitals, weight, general exam, neurologic exam, and pelvic exam with Papanicolaou's test (PAP) and Neisseria gonorrhoeae gonococcus (GC)/chlamydia cultures
3. Baseline and monitoring laboratory tests, such as complete blood count (CBC) with differential, chemistry, liver function tests (LFTs), lipid profile, chronic hepatitis serology (hepatitis B virus [HBV] and hepatitis C virus [HCV]), rapid plasma reagin (RPR), urinalysis, cytomegalovirus (CMV) and toxoplasmosis titers, CD4 count, HIV ribonucleic acid (RNA) viral load, chest x-ray (CXR), purified protein derivative (PPD) skin test, varicella-zoster titers
4. Update influenza, pneumococcal and hepatitis B vaccines
5. Pharmacologic treatment
    - Disease-specific primary antimicrobial prophylaxis:
        - Isoniazid (INH)
        - Rifampin
        - Rifabutin
        - Trimethoprim-sulfamethoxazole (TMP-SMX) DS
        - Dapsone
        - Pentamidine aerosolized
        - Dapsone plus pyrimethamine plus leucovorin
        - Azithromycin

        - Clarithromycin
    - Disease-specific secondary antimicrobial prophylaxis:
        - TMP-SMX DS
        - TMP-SMX DS, dapsone or pentamidine aerosolized
        - Sulfadiazine plus pyrimethamine plus leucovorin
        - Clindamycin plus pyrimethamine plus leucovorin
        - Clarithromycin plus ethambutol plus/minus rifabutin
        - Azithromycin plus ethambutol plus/minus rifabutin
        - Ganciclovir
        - Ganciclovir plus intraocular implant
        - Foscarnet intravenous (IV), cidofovir or valganciclovir
        - Fluconazole
        - Itraconazole
        - Amphotericin
        - Ciprofloxacin
        - Acyclovir
        - Valacyclovir
        - Famciclovir
    - Nucleoside reverse transcriptase inhibitors, such as abacavir, didanosine EC, lamivudine, stavudine, zalcitabine, zidovudine, tenofovir

      Note from the National Guideline Clearinghouse™: The U.S. Food and Drug Administration's (FDA) MedWatch Safety program distributed information from the manufacturer (Gilead Sciences, Inc) of tenofovir disoproxil fumarate (Viread®) about a high rate of early virologic failure and emergence of nucleoside reverse transcriptase inhibitor (NRTI) resistance associated mutations with the use of the drug in a once-daily triple NRTI regimen along with didanosine enteric coated beadlets (Videx EC, Bristol-Myers Squibb), and lamivudine (Epivir, GlaxoSmithKline). Based on these results, Tenofovir DF in combination with didanosine and lamivudine is not recommended when considering a new treatment regimen for therapy-naïve or experienced patients with HIV infection. Patients currently on this regimen should be considered for treatment modification. For more information, visit the FDA Web site.

    - Non-nucleoside reverse transcriptase inhibitors, such as efavirenz, delavirdine, nevirapine
    - Protease inhibitors, such as amprenavir, indinavir, lopinavir, ritonavir, nelfinavir, saquinavir
6. Patient education/counseling including pathophysiology, routes of transmission, complications/risks of disease, pharmacologic treatment, monitoring parameters (frequency and importance), drug resistance and importance of adherence, individual treatment plan
7. Consultation with or referral to infectious disease ophthalmologist/clinic and/or to infectious disease specialist/clinic or designated physician

## MAJOR OUTCOMES CONSIDERED

Not stated

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

### METHODS USED TO ANALYZE THE EVIDENCE

Review

### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

### COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

### METHOD OF GUIDELINE VALIDATION

Not stated

### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Recommendations are presented in the form of an algorithm, HIV Disease Management, accompanied by the supplemental information below. Refer to the original guideline document for recommended antiretroviral dosages.

Table A: 1993 Centers for Disease Control and Prevention (CDC) Revised Classification System for HIV Infection and Expanded AIDS Surveillance Case Definition for Adolescents and Adults*

| | Clinical Categories | | |
|---|---|---|---|
| CD4+ T-Cell Categories | (A)<br><br>Asymptomatic, acute (primary) HIV infection, or persistent generalized lymphadenopathy | (B)<br><br>Symptomatic, not A or C conditions | (C)<br><br>AIDS indicator conditions *** |
| > 500 cells/$mm^3$ or > 29%** | A1 | B1 | C1 |
| 200-499 cells/$mm^3$ or 14-29%** | A2 | B2 | C2 |
| < 200 cells/$mm^3$ or 14%** | A3 | B3 | C3 |

* Patients with AIDS indicator conditions (C1, C2, C3) and CD4 counts < 200 (A3 or B3) are reported as AIDS cases

**CD4% of total lymphocyte count

***Candidiasis, coccidioidomycosis, cryptococcosis, cryptosporidiosis, cytomegalovirus (CMV), histoplasmosis, Mycobacterium avium complex (MAC), Pneumocystis carinii pneumonia (PCP), toxoplasmosis, wasting due to human immunodeficiency virus (HIV), HIV encephalopathy, Kaposi's sarcoma, etc.

Table B: Primary Prophylaxis of Opportunistic Infections

| Initiate based on CD4 count | Organism | Recommended Regimen | Alternative Regimen | Discontinuation Criteria |
|---|---|---|---|---|

| Initiate based on CD4 count | Organism | Recommended Regimen | Alternative Regimen | Discontinuation Criteria |
|---|---|---|---|---|
| All (regardless of CD4 count) | M. tuberculosis PPD ≥ 5 mm | INH 5 mg/kg/day (max 300 mg) or 900 mg twice a week x 9 months | Rifampin 600 mg po qd or Rifabutin 300 mg po qd x 4 months | |
| | S. pneumoniae | Pneumococcal vaccine (repeat one time only in 5 years) | | |
| | Influenza virus | Influenza vaccine (one dose annually) | | |
| | Hepatitis B virus* | Hepatitis B vaccine (3 dose series) | | |
| < 200** | P. carinii | TMP-SMX DS qd, Mon.-Fri., or three times a week | Dapsone 100 mg qd or Pentamidine aerosolized 300 mg q month | CD4 count > 200 & viral load undetectable ≥ 3 months (restart if CD4 count < 200) |
| < 100*** | T. gondii | TMP-SMX DS qd | Dapsone 100 mg qd + Pyrimethamine 50 mg q week + Leucovorin 25 mg q week | CD4 count > 200 & viral load undetectable ≥ 3 months (restart if CD4 count < 200) |
| < 50 | M. avium complex | Azithromycin 1 gm q week | Clarithromycin 500 mg bid or Rifabutin 300 mg qd | CD4 count > 100 & viral load undetectable ≥ 3 months (restart if CD4 count < 50-100</strong) |

Abbreviations: INH, Isoniazid; TMP-SMX, Trimethoprim-sulfamethoxazole

*All susceptible (anti-HBc negative) patients

**Start prophylaxis if have oropharyngeal candidiasis regardless of CD4 count

*** If also antibody positive

****Primary prophylaxis for CMV and deep fungal infections is generally not recommended

Table C: Secondary Prophylaxis of Opportunistic Infections

| Indication | Organism | Recommended Regimen | Alternative Regimen | Discontinuation Criteria |
|---|---|---|---|---|
| Prior PCP | P. carinii | TMP-SMX DS qd | TMP-SMX DS Mon.-Fri., Dapsone 100 mg qd or Pentamidine aerosolized 300 mg q month | CD4 count > 200 & viral load undetectable ≥ 3 months (restart if CD4 count < 200) |
| Prior toxoplasmic encephalitis | T. gondii | Sulfadiazine 500-1000 mg po qid + Pyrimethamine 25-50 mg po qd + Leucovorin 10-25 mg po qd | Clindamycin 300-450 mg po q 6-8 hr + Pyrimethamine 25-50 mg po qd + Leucovorin 10-25 mg po qd | CD4 count > 200 & viral load undetectable ≥ 6 months* (restart if CD4 count < 200) |
| Prior disseminated disease | M. avium complex | Clarithromycin 500 mg po bid + Ethambutol 15 mg/kg po qd +/- Rifabutin 300 mg po qd | Azithromycin 500 mg po qd + Ethambutol 15 mg/kg po qd +/- Rifabutin 300 mg po qd | CD4 count > 100 & viral load undetectable ≥ 6 months* (restart if CD4 count < 100) |
| Prior end-organ disease | Cytomegalovirus (CMV) | Ganciclovir 5-6 mg/kg/day IV 5-7 days a week or for retinitis ganciclovir 1 gm po TID + SR implant q 6-9 months | Foscarnet IV 90 mg/kg/day, Cidofovir 5 mg/kg IV q 2 weeks, or Valganciclovir 900 mg po qd | CD4 count > 100-150 & viral load undetectable ≥ 6 months** (restart if CD4 count < 100-150) |
| Prior disease | Cryptococcus neoformans | Fluconazole 200 mg po qd | Itraconazole 200 mg po qd, or Amphotericin 0.6-1 mg/kg | CD4 count > 100-200 & viral load undetectable ≥ 6 months* |

| Indication | Organism | Recommended Regimen | Alternative Regimen | Discontinuation Criteria |
|---|---|---|---|---|
| | | | IV weekly - 3 times weekly | (restart if CD4 count < 100-200) |
| Prior disease | Histoplasma capsulatum | Itraconazole 200 mg po bid | Amphotericin 1 mg/kg IV weekly or Fluconazole 800 mg qd | |
| Prior disease | Coccidioides immitis | Fluconazole 400 mg po qd | Itraconazole 200 mg po bid or Amphotericin 1 mg/kg IV weekly | |
| Bacteremia | Salmonella species | Ciprofloxacin 500 mg po bid x several months | | |
| Frequent/severe recurrences | Herpes simplex virus*** | Acyclovir 400 mg po bid | Valacyclovir 500 mg po bid or Famciclovir 250 mg bid | |
| Frequent/severe recurrences | Candida*** (oropharyngeal, vulvovaginal, esophageal) | Fluconazole 100-200 mg po qd | Itraconazole 200 mg po qd | |

Abbreviation: TMP-SMX, Trimethoprim-sulfamethoxazole

*If completed ≥ 12 months of treatment asymptomatic

**If initial treatment completed, asymptomatic & regular ophthalmology exams

***Recommended only if subsequent episodes are frequent or severe

### CLINICAL ALGORITHM(S)

An algorithm is supplied for HIV Disease Management.

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation. This guideline was adapted from the following sources:

- 2001 USPHS/IDSA guidelines for the prevention of opportunistic infections in persons infected with human immunodeficiency virus. Centers for Disease Control and Prevention/Public Health Service (U.S.)/Infectious Diseases Society of America. 1999 Aug (updated 2001 Nov 28) 64 p.
- Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. Centers for Disease Control and Prevention/Department of Health and Human Services (U.S.)/Henry J. Kaiser Foundation. 1998 Dec 1 (updated 2002 Feb 4) 74 p.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate management and treatment of human immunodeficiency virus (HIV) infection in incarcerated offenders within the Texas Department of Criminal Justice

### POTENTIAL HARMS

#### Adverse Effects of Medication and Medication Interactions

- Nucleoside reverse transcriptase inhibitors (NRTIs)
    - Abacavir (ABC, Ziagen®); no drug interactions listed; adverse effects include hypersensitivity reaction characterized by fever, nausea, vomiting, malaise, anorexia, respiratory symptoms, +/-rash.
    - Didanosine EC (ddI, Videx EC®); drug interactions with tenofovir, methadone; adverse effects include peripheral neuropathy, rare pancreatitis, nausea, diarrhea
    - Lamivudine (3TC, Epivir®); no drug interactions listed; adverse effects are minimal
    - Stavudine (d4T, Zerit®); drug interactions with zidovudine, methadone; adverse effects include peripheral neuropathy
    - Zalcitabine (ddC, Hivid®); no drug interactions listed; adverse effects include peripheral neuropathy, stomatitis
    - Zidovudine (AZT, ZDV, Retrovir®); drug interactions include stavudine, ribavirin; adverse effects include initial gastrointestinal (GI) upset, headache, nail discoloration, fatigue, anemia, neutropenia, myopathy
    - Tenofovir (TNV, Viread®); drug interaction with didanosine; adverse effects include GI upset, flatulence, headache

      Note from the National Guideline Clearinghouse™: The U.S. Food and Drug Administration's (FDA) MedWatch Safety program distributed information from the manufacturer (Gilead Sciences, Inc) of tenofovir disoproxil fumarate (Viread®) about a high rate of early virologic failure and emergence of nucleoside reverse transcriptase inhibitor (NRTI) resistance associated mutations with the use of the drug in a once-daily triple NRTI regimen along with didanosine enteric coated beadlets (Videx EC, Bristol-Myers Squibb), and lamivudine (Epivir,

GlaxoSmithKline). Based on these results, Tenofovir DF in combination with didanosine and lamivudine is not recommended when considering a new treatment regimen for therapy-naïve or experienced patients with HIV infection. Patients currently on this regimen should be considered for treatment modification. For more information, visit the FDA Web site.

- Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
  - Efavirenz (EFV, Sustiva®); drug interactions with ergotamine, rifampin, rifabutin, clarithromycin, phenytoin, warfarin, carbamazepine; adverse effects include rash, central nervous system symptoms (e.g., dizziness, insomnia, vivid dreams), elevated liver function tests (LFTs), false positive cannabinoid test
  - Delavirdine (DLV, Rescriptor®); drug interactions with lovastatin, clarithromycin, rifampin, rifabutin, H2-antagonists (e.g., ranitidine), proton pump inhibitors (e.g., lansoprazole), ergotamine, dapsone, phenytoin, warfarin, carbamazepine, quinidine; adverse effects include rash, elevated LFTs, headache
  - Nevirapine (NVP, Viramune®); drug interactions with ketoconazole, rifampin, phenytoin, carbamazepine; adverse effects include rash, elevated LFTs, hepatitis
- Protease inhibitors (PIs)
  - Amprenavir (APV, Agenerase®); drug interactions with lovastatin, rifampin, rifabutin, ergotamine; adverse effects include nausea, vomiting, diarrhea, rash, elevated LFTs, hyperglycemia, fat redistribution, lipid abnormalities
  - Indinavir (IDV, Crixivan®); drug interactions with lovastatin, rifampin, rifabutin, ergotamine, carbamazepine; adverse effects include nephrolithiasis, GI intolerance, nausea, metallic taste, hyperglycemia, fat redistribution, lipid abnormalities
  - Lopinavir plus ritonavir (LPV, Kaletra®); drug interactions with lovastatin, rifampin, rifabutin, ergotamine; adverse effects include nausea, vomiting, diarrhea, asthenia, elevated LFTs, hyperglycemia, fat redistribution, lipid abnormalities
  - Nelfinavir (NFV, Viracept®); drug interactions with atorvastatin, lovastatin, rifampin, rifabutin, ergotamine; adverse effects include diarrhea, hyperglycemia, fat redistribution, lipid abnormalities
  - Ritonavir (RTV, Norvir®); drug interactions with lovastatin, amiodarone, quinidine, clozapine, rifabutin, ergotamine, desipramine, theophylline; adverse effects include nausea, vomiting, diarrhea, parasthesias, pancreatitis, taste perversion, elevated LFTs, hyperglycemia, fat redistribution, lipid abnormalities
  - Saquinavir (SQV, Fortovase®); drug interactions with lovastatin, rifampin, rifabutin, ergotamine; adverse effects include nausea, vomiting, diarrhea, rash, elevated LFTs, hyperglycemia, fat redistribution, lipid abnormalities

Note from the guideline developers: This is not a complete list of drug interactions or adverse effects.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

The pathways do not replace sound clinical judgement nor are they intended to strictly apply to all patients.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness
Staying Healthy

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Texas Tech University Managed Health Care Network Pharmacy & Therapeutics Committee. HIV disease management. Conroe (TX): University of Texas Medical Branch Correctional Managed Care; 2002 Jul. 7 p. [3 references]

### ADAPTATION

The guideline was adapted from the following sources:

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### DATE RELEASED

1996 Sep (revised 2002 Jul)

## GUIDELINE DEVELOPER(S)

University of Texas Medical Branch Correctional Managed Care - Academic Institution

## SOURCE(S) OF FUNDING

University of Texas Medical Branch Correctional Managed Care

## GUIDELINE COMMITTEE

Texas Tech University Managed HealthCare Network Pharmacy & Therapeutics Committee

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Texas Tech University Managed Health Care Network Pharmacy & Therapeutics Committee. HIV disease management. Conroe (TX): Texas Department of Criminal Justice, University of Texas Medical Branch; 1996 Sep 1 p.

## GUIDELINE AVAILABILITY

Print copies: Available from University of Texas Medical Branch (UTMB), 3009A HWY 30 West, Huntsville, TX, 77340.

## AVAILABILITY OF COMPANION DOCUMENTS

None available

## PATIENT RESOURCES

None available

## NGC STATUS

This NGC summary was completed by ECRI on March 12, 2003. The information was verified by the guideline developer on March 24, 2003.

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